Texas Commission on Environmental Quality
Comments Regarding the U.S. Environmental Protection Agency
Draft Recommended Interim Preliminary Remediation Goals for Dioxin
in Soil at CERCLA and RCRA Sites
Notice of Availability and Announcement of Public Comment Period
75 FR 0984, January 7, 2010
Docket ID No. EPA-HQ-SFUND-2009-0907

The Texas Commission on Environmental Quality (TCEQ) provides the following comments on the U.S. Environmental Protection Agency (EPA) announcement of the public comment period regarding its proposal to adopt interim preliminary remediation goals (PRGs) applicable to dioxin (2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD)) and other dioxin-like compounds in soils at Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA / Federal Superfund) and Resource Conservation and Recovery Act (RCRA / Federal Hazardous Waste) corrective action sites.

EPA proposes to substantially reduce the PRGs for dioxin in residential soils from the present value of 1 part per billion (ppb) TCDD toxicity equivalents (TEQ) to .072 ppb TCDD TEQ. For dioxin in soils at commercial/industrial sites, EPA proposes to reduce the PRG from a level within the concentration range from 5 to 20 ppb TCDD TEQ to .950 ppb TCDD TEQ. EPA expects to finalize these revised PRGs in June 2010 and that they will remain in effect in the interim until it issues the final reassessment of dioxin toxicity which it plans to accomplish by the end of 2010. EPA intends to then issue updated PRGs based on its final dioxin reassessment and to reevaluate cleanup decisions that were based on these 2010 interim PRGs in order to ensure that those cleanups remain protective of human health.

Toxicology-Based Comments:
The TCEQ provides the following comments which question the rationale for issuing revised PRGs for dioxins in soils until such time as scientifically defensible toxicity values are available upon completion of the dioxin reassessment.

- The complexity of the analysis of dioxin toxicity, the unknown outcome of the final dioxin reassessment, and the potential for significant implications associated with the interim PRGs, all indicate that EPA should allow a longer comment period for stakeholders to prepare comments. The allotted 50 days to prepare comments does not provide for an appropriate level of peer review and undermines confidence in the interim PRG values. At a minimum, EPA should extend the comment period at least 60 days past the February 26 deadline to allow stakeholders to perform a more detailed review of the volumes of relevant information and to comment on problematic issues associated with the interim PRG calculations.

- The draft interim PRG document states that the proposed interim PRGs are informed by the best available science at this time.[1] The document negates this claim when it also states "there is uncertainty associated with these draft recommended interim PRGs because they do not take into account peer review

[1] Page 2, www.epa.gov/superfund/policy/remedy/pdfs/Interim_Soil_Dioxin_PRG_Guidance_12-30-09.pdf

comments on the new science that was reviewed by the National Academy of Sciences (NAS), and new science that was released since the NAS review."[2] This contradiction calls into question the transparency of the PRG development process. The proposed interim PRGs are not based on the best available science at this time. Specifically, the carcinogenic oral slope factor (SFo) (EPA, 1985) and the non-carcinogenic chronic minimum risk level (MRL) (ATSDR, 1998) toxicity factors used in the PRG calculations are 25 and 12 years old, respectively. Also, the proposed interim PRGs do not take into account the National Toxicology Program (NTP) animal studies (NTP, 2004 and 2006) released after the 2003 draft reassessment. The final dioxin reassessment will provide a better basis for revised PRGs provided the recommendations from the NAS are appropriately incorporated into the final analysis (e.g., incorporation of nonlinear and probabilistic approaches, quantitative characterization of uncertainty and variability in risk, transparency in selection of key data, and assessing dose-response model goodness of fit). The TCEQ concludes that there is sufficient uncertainty regarding dioxin toxicity that EPA should not issue revised dioxin PRGs until all stakeholders have had an opportunity to help determine the best science available at this time.

- EPA did not include the 2007 California EPA SFo[3] used for the draft drinking water public health goal (CalEPA, 2007) when discussing the available SFo values for use in PRG calculations. The CalEPA's 2007 SFo is based on a 2004 NTP study (NTP, 2004) and is the only SFo available that is informed by the latest science. The CalEPA and others consider that study to be a superior basis for SFo calculations, due to its careful design and conduct and the improved survival rate, as compared to the 1978 Kociba study (Kociba RJ, Keyes DG, Beyer JE, et al., 1978) adopted by EPA for its 1985 SFo[4] and used in the interim PRG calculation. The CalEPA's 2007 SFo is six times less conservative than the EPA's 1985 SFo and is based on the latest and perhaps best animal study conducted to date for carcinogenic risk assessment.

- The monkey study (Schantz SL, Ferguson SA, Bowman RE., 1992) data which serve as the basis of the 1998 non-cancer toxicity factor[5] (ATSDR, 1998) used by EPA for the interim PRG calculations were excluded from the quantitative assessments of tolerable daily intakes by several international agencies.[6] Substantial amounts of non-TCDD compounds (e.g., polychlorinated dibenzo-p-dioxins, polychlorinated dibenzo-p-furans, and dioxin-like polychlorinated biphenyls (PCBs)) were found to be contributing to the TCDD TEQ concentrations for several of the TCDD-exposed monkeys and other non-exposed monkeys (Alward LL, Lakind JS, Hays SM., 2008). Use of the daily dose of TCDD from this study to derive the chronic MRL is problematic, since that value likely underestimates the TCDD TEQ concentration that was present at the time of the observed effects.

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[2] Page 4, www.epa.gov/superfund/policy/remedy/pdfs/Interim_Soil_Dioxin_PRG_Guidance_12-30-09.pdf
[3] 26,000 per mg/kg-day
[4] 156,000 per mg/kg-day
[5] ATSDR's chronic MRL
[6] Joint Expert Committee on Food Additives (JECFA) of the World Health Organization (WHO) and Food and Agricultural Organization (FAO), European Commission Scientific Committee on Foods (ECSCF), and United Kingdom Committee on Toxicity (UKCOT).

- EPA should develop a reasonable estimate of relative bioavailability (less than 1) of soil dioxin from available studies and then use that value in the PRG calculations. EPA assumes the dioxin bioavailability from soil is the same as the dioxin bioavailability in the toxicological studies used as the basis for the toxicity factors, i.e., the SFo and chronic MRL.[7] EPA's use of a relative bioavailability of 1 in the interim PRG calculations[8] demonstrates this assumption, which is questionable since animals in toxicological studies are typically dosed with more bioavailable forms of chemicals than those occurring in soil.

- The draft interim PRG document[9] also mentions that EPA is requesting comments on the utility of alternative PRGs at a 1E-06 excess cancer risk level. The above comments also apply to these alternative PRGs with the additional concern that setting PRGs within or below background concentrations is not feasible from a compliance perspective. Such an approach could result in costly studies to determine site-specific background concentrations whenever TCDD or other dioxin-like compounds are present at a site.

Implementation-Based Comments:
The TCEQ provides the following implementation-based comments which conclude that EPA should not issue revised PRGs for dioxin and dioxin-like compounds in soils until such time as it completes the final reassessment of dioxin toxicity. However, if EPA decides to issue the interim PRGs, then it should, previously or concurrently, release additional guidance that more specifically discusses how the interim PRGs are to be applied to active and closed dioxin sites. Also, EPA should clarify in such guidance that it does not intend to use revised PRGs, prior to its completion of the final dioxin reassessment and issuance of associated PRGs, to conclude that any site that has been appropriately evaluated and/or remediated in response to its 1998 dioxin PRGs requires additional response to be protective of human health.

- EPA is not being consistent with its own logic presented in the 1998 Office of Solid Waste and Emergency Response (OSWER) memorandum which memorializes the dioxin cleanup levels historically used by EPA at CERCLA and RCRA cleanup sites. That memorandum states, "The Office of Solid Waste and Emergency Response does not believe it is prudent to establish new, and possibly varying, precedents for Superfund or RCRA dioxin levels just prior to the release of this reassessment report." (EPA, 1998). The TCEQ concurs with EPA's previously stated view that it should not release interim PRGs just prior to the release of the final dioxin reassessment.

- EPA states that it intends to issue interim PRGs for dioxin this June and that it expects to complete the dioxin reassessment by the end of 2010. If this is the case, then the TCEQ questions the purpose and utility of EPA issuing interim PRGs when those PRGs are likely to change, after being reassessed, in only six or seven months. On the other hand, when EPA stated its expectation to complete the dioxin reassessment by the end of 2010, it also stated that completion by that date was

[7] Page 11, www.epa.gov/superfund/policy/remedy/pdfs/Interim_Soil_Dioxin_PRG_Guidance_12-30-09.pdf
[8] Pages 23-24, www.epa.gov/superfund/policy/remedy/pdfs/ Interim_Soil_Dioxin_PRG_Guidance_12-30-09.pdf
[9] Page 13, www.epa.gov/superfund/policy/remedy/pdfs/ Interim_Soil_Dioxin_PRG_Guidance_12-30-09.pdf

"subject to further consideration of the science and the scope and complexity of the revisions that will need to be made."[10] EPA has been working since 2004 to incorporate the comments provided by the NAS with regard to its last version of the dioxin reassessment issued in 2003. When EPA issues its proposed final dioxin reassessment, it should expect comments regarding whether it has appropriately addressed the concerns expressed by the NAS in 2004 and whether new research regarding dioxin toxicity has been appropriately incorporated into the reassessment. So it seems reasonable to expect that EPA will need more time, and perhaps significantly more time, beyond the end of 2010 to complete the dioxin reassessment. In this circumstance, the TCEQ objects to the issuance of interim PRGs for dioxin in soils that are not based on the best science currently available and that could remain in effect for an unknown number of years. Both of these possible circumstances support the conclusion that EPA should wait until the final dioxin reassessment is completed before it issues revised PRGs for dioxins.

- The discussion that EPA provides on implementation issues in the public review draft of the recommended interim PRGs for dioxins in soils does not provide sufficient detail for stakeholders to be able to evaluate how EPA intends to use the revised PRGs. Additional detail is needed which describes how EPA intends its regions to reevaluate CERCLA and RCRA corrective action sites that have been evaluated and/or remediated in the intervening period between its issuance of the interim PRGs and the final PRGs that are to be consistent with the final dioxin reassessment. Also, the document does not discuss whether EPA intends to use the interim PRGs when it reevaluates CERCLA and RCRA corrective action sites that have been evaluated and/or remediated using its 1998 PRGs.[11] However, EPA does mention that its regions should "consider" this public review draft document on the recommended interim PRGs when performing five-year-reviews of CERCLA sites containing dioxin or dioxin-like compounds to determine whether the original remedy stated in the Record of Decision remains protective. EPA should release additional guidance no later than the issuance of any interim PRGs that more specifically discusses how the interim PRGs are to be applied to active and closed dioxin sites. This guidance should specifically address how PCB sites that have only Arochlor data, and for which TCDD TEQs cannot be calculated, are to be handled. Also, EPA should clarify in this guidance that it does not intend to use the interim PRGs, prior to its completion of the final dioxin reassessment, to conclude that any site that has been appropriately evaluated and/or remediated in response to its 1998 dioxin PRGs requires additional response to be protective of human health.

[10] Page 1, www.epa.gov/superfund/policy/remedy/pdfs/ Interim_Soil_Dioxin_PRG_Guidance_12-30-09.pdf

[11] Pages 2, 14-16, www.epa.gov/superfund/policy/remedy/pdfs/ Interim_Soil_Dioxin_PRG_Guidance_12-30-09.pdf

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